RISK ASSESSMENT & SCIENTIFIC ASSISTANCE DEPARTMENT

CALL FOR PROPOSALS

SIMPLIFIED FORM OF GRANT - FINANCING BASED ON ACHIEVEMENT OF RESULTS[1]

Call reference: GP/EFSA/FDP/2022/02
Call title: Refining the methodology for verifying the GLP compliance of studies submitted within an application for regulated products
Project/Process code: EPA05.01-L3
Budget line: 3210

Restricted to **the list of competent organisations** established by the Authority's Management Board in application of article 2 the Commission Regulation (EC) No 2230/2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the Authority's remit.

1 Article 125.1(a) FR

INDICATIVE PROCEDURE TIMETABLE

Milestone	Date[2]	Comments
Launch date	**20/06/2022**	Date of call publication on EFSA's website.
Deadline for applicants to raise clarification questions to EFSA	~~13/09/2022~~ 04/10/2022	If, after having read this Call for proposals and guide for applicants, you have any questions, you may address them to EFSAProcurement@efsa.europa.eu by indicating the Call reference.
Deadline for EFSA to reply to clarification questions	~~15/09/2022~~ 06/10/2022	Replies will be provided on EFSA's webpage where this Call is published and which the applicants are requested to consult regularly.
Deadline for submission of proposals Any proposal posted after the final deadline will automatically be rejected.	~~**21/09/2022**~~ **12/10/2022**	You can submit your proposal: - either by post (registered mail) or by courier not later than **21/09/2022**, in which case the evidence of the date of dispatch shall be constituted by the postmark or the date of the deposit slip, to the address indicated below. The applicant submitting a proposal by post or by courier is requested to send an informative e-mail to EFSAProcurement@efsa.europa.eu. - or delivered by hand **not later than 12.30 hours (Italian time) on ~~21/09/2022~~ 12/10/2022** to the address indicated below. In this case, a receipt must be requested from EFSA as proof of submission, signed and dated by the staff member in EFSA Post Office who accepted the delivery. The EFSA Post Office is open from 8.30 to 12.30 Monday to Friday. It is closed on Saturdays, Sundays and EFSA holidays. Submission by post, courier or hand to this address: *European Food Safety Authority - EFSA* *For the attention of – Mrs Laura Perati, Finance Unit (Procurement Team)* *Via Carlo Magno 1/A, I – 43126 Parma, Italy* Proposals must be submitted using the double envelope system. The outer envelope should be sealed with adhesive tape, signed across the seal and carry the following information: - *"CALL FOR PROPOSALS GP/EFSA/FDP/2022/02– NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT".* - name of the applicant - **the posting date should be legible on the outer envelope**
Notification of the evaluation	October/November	Estimated

[2] All times are in the time zone of the country of the EFSA.

results	2022	*Attention: outcome of the present call will be communicated to all applicants to the e-mail address indicated in their proposal. Accordingly, applicants who have submitted proposals under the present call are strongly invited to check regularly the inbox in question.*
Grant agreement(s) signature	Nov/Dec 2022	Estimated

Provide EFSA with feedback:
If you considered applying to this call for proposals but finally decided not to do so, your feedback and reasoning for such a decision would be very much appreciated. Please address it to: EFSAProcurement@efsa.europa.eu. EFSA will process any feedback confidentially in order to improve the quality of its future grant calls.

TABLE OF CONTENT:

ANNEXES:

- Annex 1: Draft grant agreement
- Annex 2: Application form
- Annex 3: Legal entity form (download template here)
- Annex 4: Financial identification form (download template here)
- Annex 5: Declaration on honour for exclusion criteria
- Annex 6: Declaration on honour for selection criteria
- Annex 7: Simplified financial statement
- Annex 8: Declaration on confidentiality

1. GRANT OPPORTUNITY AND CONDITIONS

1.1 LEGAL FRAMEWORK

Article 36 of the Regulation (EC) 178/2002[3] of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety foresees the possibility to financially support networking of organisations operating in the fields within the EFSA's mission.

In particular, Article 36 (1) stipulates that the Authority shall promote the European networking of organisations operating in the fields within the Authority`s mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework, the development and implementation of joint projects[4], the exchange of expertise and best practices in the fields within the Authority`s mission.

On the 19th December 2006 the Management Board, acting on a proposal from the Executive Director, drew up a list of competent organisations designated by the Member States which may assist EFSA, either individually or in networks, with its mission. This list is regularly updated by EFSA's Management Board.

The **Commission Regulation (EC) 2230/2004 of 23 December 2004** laying down detailed rules for the implementation of the European Parliament and Council Regulation (EC) 178/2002 with regard to the network of organisations operating in the fields within the EFSA's mission specifies in Article 4 that tasks may be entrusted by the Authority to organisations on the list of competent organisations. The present call specifically focuses on tasks defined in Article 4(3) thereof, i.e.:

- Art. 4(3), first indent -disseminating best practices and improving methods of collecting and analysing scientific and technical data, particularly for the purposes of facilitating comparability and producing a Community-level summary;
- Art. 4(3), second indent - collecting and analysing specific data in response to a common priority;
- Art. 4(3), third indent - collecting and analysing data with a view to facilitating risk assessment by the Authority.

Article 5 of the Commission Regulation (EC) 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of the European Parliament and Council Regulation (EC) 178/2002 with regard to the network of organisations operating in the fields within the EFSA's mission specifies that the financial support to the networking organisations shall take the form of subsidies (grants) awarded in accordance with the EFSA's financial regulation and implementing rules.

The present Call for proposals and guide for applicants (hereinafter referred to as "the Call") is procedurally governed by Regulation (EU, Euratom) 2018/1046[5] of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No

[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF

[4] Project is frequently referred to in this Call as "action", in line with EU Financial Regulation terminology.

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1046&from=IT

1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012.

This call is based on **EFSA's 2022 Work Programme for grants and operational procurements** as presented in Annex XII of the Programming Document 2022 – 2024, available on the EFSA's website[6].

SIMPLIFIED FORM OF GRANT - FINANCING BASED ON ACHIEVEMENT OF RESULTS

Financing based on achievement of results as opposed to financing based on cost is a new type of grant introduced in the EU financial Regulation 2018. This type of grant gives advantages on an administrative level to both EFSA and the beneficiaries. The below table illustrates the main changes.

- **Co-financing principle is not applicable**
- **No-profit principle is not applicable**
- **Estimated budget is not requested**
- **The concept of eligible/non eligible costs is no longer relevant**
- **Payments are done based on approval of deliverables. No need for EFSA to calculate the final grant amount based on spending and no need for the beneficiary to submit supporting documents for incurred costs.**

[6] https://www.efsa.europa.eu/sites/default/files/event/mb-20211216/C05.SPD-2022-2024-4.mb211216-a2.pdf

1.2 BACKGROUND AND MAIN OBJECTIVE OF THE CALL

BACKGROUND

Good Laboratory Practice (GLP) is a quality system that embodies a set of principles that provides a framework within which studies are planned, performed, monitored, recorded, reported and archived. Studies submitted to EFSA as part of an application for market authorisation of regulated products[7] that are claimed to comply with GLP principles provide a uniform basis for their quality in particular in terms of reproducibility of results.

With the purpose of enhancing the verification of the quality of studies, EFSA started to develop a GLP verification checklist in accordance with the OECD guidance for Receiving Authorities (like EFSA) on the evaluation of the GLP compliance status of non-clinical safety studies submitted for regulatory purposes[8]. With the support of its Working Group on Good Laboratory Practice[9], EFSA piloted the implementation of this verification checklist on a limited number of studies. However, considering the vast amount of studies submitted to EFSA, further refinement of the methodology is required to make the checklist fit-for-purpose to enable its implementation on a routine basis during the evaluation of an application while ensuring the critical elements of the checklist to be implemented.

Furthermore, as part of its quality programme, EFSA selects on an annual basis a number of studies submitted in applications for regulated products, to be audited by the national GLP Monitoring Authorities. The criteria for the selection of studies for its GLP Annual Audit Programme are described in EFSA's Standard Operating Procedure[10] and concern applications for different regulated products.

MAIN OBJECTIVE OF THE CALL

The objective of this grant is to **identify Art.36 partner organisation/s that can support EFSA** in further refining the methodology for verifying the compliance of GLP studies submitted within an application for regulated products considering the below standards:

- Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP);
- Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice (GLP) and the verification of their applications for tests on chemical substances
- state-of-the-art OECD Principles on Good Laboratory Practice (GLP).[11]

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[7] Regulated products include substances used in food and feed (such as additives, enzymes, flavourings, and nutrient sources), food contact materials and pesticides, genetically modified organisms, food-related processes and processing aids. EFSA's regulated products mandate also includes evaluating the scientific substantiation of nutrition and health claims (https://www.efsa.europa.eu/en/applications/regulatedproducts).

[8] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-JM-MONO(2019)25%20&doclanguage=en

[9] https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/apdesk

[10] EFSA's SOP_022_S: Selection of studies performed in compliance with Good Laboratory Practice for audit purposes. https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/SOP-022_S.pdf.

[11] https://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

Competent organisations will contribute to the development of EFSA's GLP quality programme and enhance the GLP compliance check of studies that are submitted to EFSA in the different regulatory domains. The competent organisation will share their knowledge with EFSA in the verification of quality standards of studies for the different sectoral legislations and benefit from the methodology developed within this grant. In addition, competent organisations can cooperate with Member States/Competent Authorities (e.g. GLP Monitoring authorities) for performing their tasks.

In the future, as a follow-up to this grant, EFSA might consider the launch of another call for proposals for implementing the GLP compliance verification in a more systematic way and on a larger scale.

1.3 SPECIFIC OBJECTIVES OF THE CALL/TASKS ENTRUSTED

The specific objectives of the call are the delivery of the following tasks:

1. Establish a GLP verification methodology and tools (e.g. through a fit for purpose GLP verification checklist) to facilitate the compliance check of the GLP status of studies as part of applications submitted to EFSA, for the different regulated products:
    a. To define the timelines for verifying the GLP compliance of studies in order to ensure that the outcome of the verification check is available on time to be considered as part of the completeness/suitability/admissibility check of the respective application;
    b. To enable its implementation on a routine basis during the evaluation of an application while ensuring the critical elements of the checklist are properly implemented, while keeping track of the GLP status of studies for which the verification check has been concluded;
    c. To enable to select/prioritise the studies that require further scrutiny (e.g. during the risk assessment and/or by the GLP monitoring authority);
    d. To define options for addressing GLP findings (e.g. by ranking the severity of a GLP finding and defining the corresponding follow-up action);
    e. To define the kind of additional sources of information needed (e.g. when the information/documentation required is not included in the study report);
    f. To define in which cases the GLP Monitoring Authorities need to be consulted;
    g. To enable to conclude on the GLP claim of the study.
2. Test the GLP verification process/tool with a defined number of GLP studies (estimated 1000) across different regulatory areas in a pilot study.
3. To provide an analysis of the effort required for verifying the GLP compliance of a study (time, staff) and a proposal of type and number of studies from the different application areas that would require specific attention for a GLP compliance check, based on the results of the pilot study.
4. Develop a hands-on training program on the developed GLP verification methodology/tools and provide training to EFSA staff/experts/contractors and Member States.

Performance of the tasks and ownership of the results

The tasks will be conducted by one or more staff members of the partner.

The ownership of the delivered outputs as a result of these tasks will be vested solely in EFSA and EFSA will be solely responsible of the results of the tasks performed. Only with **EFSA`s prior written permission** the beneficiary will be allowed to use the outputs resulting from the entrusted tasks.

During the performance of the entrusting tasks, the staff of the partner:

- Shall carry out their duties and conduct themselves with the interests of EFSA in mind. They shall neither seek nor take instructions from any government, authority, organisation, or person outside EFSA in relation to the execution of the specific tasks entrusted. They shall carry out the duties assigned to them objectively and impartially.
- Shall be fully subject to the EFSA Policy on Independence [1] and the Decision of the Executive Director on Competing Interest Management [2]. They will submit a Declaration of Interest which will be screened according to the rules applicable to the external experts contributing to the EFSA's work (Articles 6-8) and the rules applicable to screening of Declarations of Interest in the context of procurement and grant awarding procedures (Article 15-16).
- Shall refrain from any unauthorised disclosure of information received in the line of duty, unless that information has already been made public or is accessible to the public. EFSA will grant the staff of the partner/beneficiary access to confidential information in order to perform the tasks. They will therefore be required to sign a declaration concerning confidentiality before commencing the performance of tasks (Annex 8).
- Should a GLP verification assigned in the pilot relate to a study upon which the assigned staff has a potential conflict of interest, EFSA must be immediately notified so that EFSA may decide not to assign that specific study.

The working language for performance of tasks will be English.

1.4 ELIGIBLE ORGANISATIONS

In order to achieve the main objective of the call, the proposal can be submitted by **one eligible organisation or by a consortium of eligible organisations.** In case of a consortium, one of the partners must be identified in the proposal as the consortium leader. The applicant is responsible for identifying consortium partners.

To be eligible, the applicant and in case of a consortium the partner/s must be on the list of competent organisations designated by the Member States in accordance with Article 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004. This list is regularly updated by EFSA Management Board. You may consult the list on EFSA's website at http://www.efsa.europa.eu/en/networks/art36.htm.

An applicant interested in joining the list should contact its national Focal Point, which will explain the procedure. Contact details of the Focal Points are available on the EFSA website here.

1.5 ROLES AND RESPONSIBILITIES

A) If the proposal is submitted by a consortium:
For proper understanding of this call it is also important to have clarity on the used terminology in respect of the involved organisations and their roles.

- **The Applicant** submits the project proposal/grant application to EFSA on behalf of the consortium. The applicant is the leading entity of the consortium. There can be only one applicant in project proposal/grant application.
- **The Partner** is the other entity in the consortium. There can be a minimum of one partner or preferably more partners.

Once the grant is awarded the grant agreement is signed between EFSA, the applicant and all partners. However, the partners do not sign themselves the grant agreement. They give to the applicant, if they agree so, a mandate (template will be provided by EFSA), where they authorise the applicant to sign the grant agreement, and any possible amendments to it, also on their behalf. This facilitates the signature process where only two signatures need to be collected, one from EFSA and one from the applicant. As soon as the grant agreement is signed the applicant becomes **the Coordinator** and its partner/s become **the Co-Beneficiary/ies**. The coordinator and co-beneficiary/ies are together referred to as **the Beneficiaries**. The beneficiaries are jointly and severally liable for the technical implementation of the project as described in the proposal which will become annex 1 of the grant agreement. If a beneficiary fails to implement its part of the project, the other beneficiaries become responsible for implementing its part.

Regarding **the coordinator**, please note also the following important roles:

- Take part in implementing the project;
- Monitors that the action is implemented properly;
- Act as the intermediary for any communication between the consortium and EFSA;
- Receive and answers all claims EFSA might have in relation to the implementation of the project;
- Request and review any documents or information required by EFSA and verify their completeness and correctness before passing them on to EFSA;
- Inform EFSA and the partner/s of any event that is likely to substantially affect the implementation of the project;
- Submit the deliverables and reports to EFSA;
- Request and receive payments from EFSA and distribute the funds to partner/s without unjustified delays;

The coordinator may not delegate the above-mentioned tasks to the Co-Beneficiary/ies.

Regarding **the other beneficiary/ies**, please note also the following important roles:

- Take part in implementing the project;
- Forward to the coordinator the data needed to draw up the reports and other documents required under the grant agreement;
- Inform the coordinator of any event or circumstances likely to substantially affect or delay the implementation of the project.

B) If the proposal is submitted by a sole applicant:

For proper understanding of this call it is also important to have clarity on the used terminology in respect of the involved organisations and their roles.

- **The Applicant** submits the project proposal/grant application to EFSA. There can be only one applicant in project proposal/grant application.

As soon as the grant agreement is signed the applicant becomes the beneficiary. The beneficiary is liable for the technical implementation of the project as described in the proposal which will become annex 1 of the grant agreement.

Regarding **the beneficiary**, please note also the following important roles:

- Take part in implementing the project;
- Monitors that the action is implemented properly;
- Communicate with EFSA;

- Receive and answer all claims EFSA might have in relation to the implementation of the project;
- Request and review any documents or information required by EFSA and verify their completeness and correctness before passing them on to EFSA;
- Inform EFSA of any event that is likely to substantially affect the implementation of the project;
- Submit the deliverables and reports to EFSA;
- Request and receive payments from EFSA.

1.6. POSSIBILITY OF IMPLEMENTING CONTRACTS AND SUBCONTRACTING

Subcontracting is not permitted.

1.7 DURATION, MEETINGS AND REPORTING

The maximum duration of the project under this call is **18 months (after the kick-off meeting).**

The below mentioned meetings with EFSA are foreseen:

1. **Kick off meeting (physical or tele-meeting)**: The kick-off meeting is regarded as the start of the project and takes place no later than **one month** after the signature of the grant agreement. At this meeting, the beneficiary will explain their proposal and details of the project will be discussed. The objectives, the tools/format, the different reports' structure and timeframe will be clarified, including the timelines for receiving the GLP studies from EFSA and for receiving the GLP findings from the beneficiary. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
2. **Interim meeting N.1 (tele-meeting) will be held 3 months after the start of the project**: The purpose of this meeting is to present the different steps and associated tools of the GLP verification methodology (described in point 1 under the specific objectives of the call) and any problems or difficulties encountered during the testing of the first batch of studies (circa 100), along with their GLP findings and an indication of the effort required per study/application type. During the same meeting the proposed approach for implementing the methodology/tools for the second batch of studies will be discussed. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
3. **Interim meeting N.2 (tele-meeting) will be held 5 months after the start of the project**: The purpose of this meeting is to present the different steps and associated tools of the GLP verification methodology (described in point 1 under the specific objectives of the call) and any problems or difficulties encountered during the testing of the second batch of studies (circa 100), along with their GLP findings. The proposed GLP verification methodology, tools and GLP findings of the first two batches of studies, along an indication of the effort required per study/application type, will be described in detail in the report described as Deliverable D1. During the same meeting the proposed approach for implementing the methodology/tools for the third batch of studies, including the selection of studies (circa 400) based on the outcome of the first deliverable D1, will be discussed. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
4. **Interim meeting N.3 (tele-meeting) will be held 9 months after the start of the project:** The purpose of this meeting is to present and discuss the progress of piloting the verification methodology and tools with the third batch of studies (circa 400), along with their GLP findings and the effort required per study/application type. EFSA might here, as well, propose additional points to be evaluated in addition to those previously established. The

results will be then described in detail in the report described as Deliverable D2. During the same meeting the proposed approach for implementing the methodology/tools for the fourth batch of studies, including the selection of studies (circa 400) based on the outcome of the second deliverable D2, will be discussed. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

5. **Interim meeting N.4 (tele-meeting) will be held 13 months after the start of the project:** The purpose of this meeting is to present, discuss the follow-up of the piloting exercise to further fine-tune the GLP verification methodology and tools tested on the fourth batch of studies (circa 400), along with their GLP findings and the effort required per study/application type. EFSA might here, as well, propose additional points to be evaluated in addition to those previously established. The results will be then described in detail in the report described as Deliverable D3. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
6. **Interim meeting N.5 (tele-meeting) will be held 15 months after the start of the project:** The purpose of this meeting is to present and discuss the results of the piloting exercise on the GLP verification methodology and tools tested on all studies (from the four batches), along with their GLP findings. Both results and suggestions will then be detailed in the report (Deliverable D4), including a detailed description of the finalised GLP verification methodology, of the tools and GLP findings, as well as of the efforts required per study/application type. In addition, the purpose of this meeting is also to present, discuss and define the training program on the GLP verification methodology and tools for EFSA staff and Member States. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
7. **Final meeting (tele-meeting) will be held 18 months after the start of the project.** The purpose of this meeting is to present the feedback on training materials and performance, which will be described in detail in the report described as Deliverable D5. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

The tools/format for keeping track of the GLP status of studies for which the verification check has been concluded, needs to be compatible with EFSA's IT existing tools and to be agreed with EFSA during the kick-off meeting. Minutes of the meetings and below mentioned deliverables and reports must be drafted in UK Standard English language. They will include a full description of the process implemented. A draft of the deliverables should be provided one week ahead the corresponding meeting and be finalised one week after the meeting. All deliverables created within this project may be subject to publication at EFSA's discretion.

The performance of the tasks described in section 1.3 shall lead to the following outputs:

1. **Deliverable D1 (Deadline: 5 months after the start date of the project).** The deliverable D1 is the report that will describe the proposed GLP verification methodology and tools (e.g prioritisation of GLP findings that require further scrutiny, different options allowing a time-efficient evaluation of the GLP status of studies, follow-up actions, exact tools/format definition, etc), GLP findings and effort required per study/application type, based on the delivery of the testing of the first two batches of studies (circa 200).

2. **Deliverable D2 (Deadline: 9 months after the start date of the project).** The deliverable D2 is a report that will describe the results of the further elaboration and refinements of the GLP verification methodology and tools based on the third batch of studies (circa 400), including GLP findings and effort required per study/application type.

3. **Deliverable D3 (Deadline: 13 months after the start date of the project).** The deliverable D3 is a report describing the results of the further elaboration and refinements of the GLP verification methodology and tools based on the fourth batch of studies (circa 400), including GLP findings and effort required per study/application type.

At the time of delivery of Deliverable 3, the partner is expected to have completed the testing of an estimated number of 1.000 GLP studies.

4. **Deliverable D4 (Deadline: 15 months after the start date of the project).** The deliverable D4 is a report describing an integrated overview of the results achieved of the finalised GLP verification methodology and tools based on all batches of studies, including an overview of GLP findings.

5. **Deliverable D5 (Deadline: 18 months after the start date of the project).** The deliverable D5 contains the GLP training material to EFSA staff/experts/contractors and Member States and the feedback on the training provided.

Foreseen planning of meetings and deliverables

Time from kick-off meeting	Month 1	Month 3	Month 5	Month 9	Month 13	Month 15	Month 18
Deliverables			D1	D2	D3	D4	D5
Meetings	Kick-off meeting	Interim meeting N.1	Interim meeting N.2	Interim meeting N.3	Interim meeting N.4	Interim meeting N.5	Final Meeting

Foreseen milestones and corresponding project completion rate

Milestones	Project completion rate %
Approval of Deliverable 1	30%
Approval of Deliverable 2	25%
Approval of Deliverable 3	25%
Approval of Deliverable 4	10%
Approval of Deliverable 5	10%
Approval of all Deliverables	**100%**

1.8 PAYMENTS

The following payment scheme will be applied to the signed grant agreement:

- **pre-financing payment**, upon grant agreement entry into force, without need for a request for payment, **between 10% and 40%** of the maximum grant amount set out in the grant agreement; the aim of the pre-financing is to provide the beneficiaries with a float; it remains the property of the EU until the payment of the balance. Please note the exact amount of pre-financing will be determined at the time of awarding the grant;

- **interim payment**, based on the request for interim payment, **up to 70%** of the maximum grant amount (including the pre-financing payment). The interim payment is subject to the approval by EFSA of deliverables D1, D2 and D3;

- **final payment (payment of the balance)**, the amount due as the balance payment is calculated by EFSA by deducting from the final EFSA grant amount the total amount of pre-financing and interim payments already made. The payment is subject to the approval by EFSA of Deliverables D4 and D5.

1.9 GRANT PRINCIPLES

The financial help provided by EFSA under this Call is a grant governed by the EU Financial Regulation referred to in part 1.1. Accordingly, the grant awarded following this Call must comply with the following principles:

- **Co-financing**: Not applicable

- **No-profit**: Not applicable

- **Non-retroactivity**: A grant may be awarded for a project which has already begun provided that the applicant can demonstrate the need for starting the action prior to signature of the grant agreement. In such cases, costs eligible for financing shall not have been incurred prior to the date of submission of the grant application. No grant may be awarded retrospectively for a project already completed.

- **Non-cumulative**: A project may only receive one grant from the EU budget. In no circumstances shall the same costs be financed twice by the Union budget. To ensure this, the applicant shall indicate the sources and amounts of Union funding received or applied for the same project or part of the project or for its functioning during the same financial year as well as any other funding received or applied for the same project.

1.10 EFSA GRANT CONTRIBUTION

The grant will take the form of a financing not linked to costs amounting to **maximum 250.000 euro**. Payment will be conditioned on the achievement of the results described in point 1.7. In case the action is not implemented in line with the project, EFSA will reduce the maximum contribution initially estimated, in line with the actual implementation of the action.

EFSA intends to fund one proposal following this Call. However, EFSA reserves the right not to award all the funds available at any cost, e.g. if the quality of submitted proposals will not be satisfactory.

Please note that EFSA has also the right not to award any grant and to cancel the whole grant procedure at any time before the signature of the grant agreement without any compensation to be paid to the applicant.

If the amount granted is lower than the funding needed by the applicant, it is up to the latter to find supplementary financing or to cut down on the total cost of the project without diluting either the objectives or the content.

1.11 PUBLICITY

The beneficiary/ies is/are expected to follow the rules on visibility of EFSA funding set out in Article II.8 of the grant agreement.

According to Article 38 of the EU Financial Regulation EFSA is bound to publish information on recipients of its grants at its website. Such publication shall take place no later than 30 June of the year following the financial year in which the grants were awarded and shall cover these data of the beneficiaries:

- name of the beneficiary,
- address of the beneficiary,
- subject of the grant,
- amount awarded.

1.12 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing your application in the context of this grant procedure, will involve the recording and processing of personal data (i.e. the name, any CV and contact details and/or financial details of individuals contained in your application) pursuant to Regulation (EU) 2018/1725[12].

Unless indicated otherwise, the questions and any personal data requested are required to evaluate the application in accordance with the specifications of the Call and the data will be processed solely for that purpose.

Detailed information on the processing of personal data in the context of grant award procedures of EFSA is given in the Privacy Statement available on the EFSA website. This on-line privacy statement details the following:

- the legal basis, purpose and controller of the personal data processing;
- what personal information EFSA is collecting and/or further processing;
- to whom personal data is disclosed;
- what technical means are applied for data processing and way in which EFSA secures the information;
- how data subjects can access, modify and delete their information;
- how long EFSA keeps the personal data;
- the contact details for data subjects to exercise their rights;
- the right of recourse to the European Data Protection Supervisor.

Personal data may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 136 - 140 of the Financial Regulation. For more information see the Privacy Statement on:
http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm).

[12] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC.

In case the implementation of activities under an awarded grant entails the processing of personal data, the beneficiary shall comply with the relevant rules in the **draft Grant Agreement (Annex 1)** as a data processor of EFSA.

1.13 PUBLIC ACCESS TO DOCUMENTS

In the general implementation of its activities and for the processing of grant procedures in particular, EFSA observes Regulation (EC) N° 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

1.14 OPEN ACCESS

EFSA is committed to the publication of grant outputs on the EFSA website and/or in the Knowledge Junction[13] in order to improve transparency, reproducibility and evidence reuse. The Knowledge Junction runs on the EU-funded Zenodo research-sharing platform where uploaded items receive a unique Digital Object Identifier to make them citable. Any part of the output resulting from the action under this grant may be published (at EFSA's discretion) on the Knowledge Junction with attribution to the beneficiary.

[13] Learn more at http://www.efsa.europa.eu/en/press/news/161114

2. SELECTING PROPOSALS

The Evaluation Committee established by EFSA specifically for this call will evaluate the submitted proposals in five steps:

1. Verification of submission requirements (see 2.1)
2. Eligibility criteria (see 2.2)
3. Exclusion criteria (see 2.3)
4. Selection criteria (see 2.4)
5. Award criteria (see 2.5)

If the proposal fails at any step it is automatically excluded from further evaluation. EFSA may contact the applicant during the evaluation process if there is a need to clarify certain aspects or for the correction of clerical mistakes.

2.1 VERIFICATION OF SUBMISSION REQUIREMENTS

The following will be verified:

- The proposal was submitted within the deadline for submission of proposals.
- The proposal is submitted on the **EFSA application form (Annex 2)**.
- The proposal is duly signed by the authorised representative of the applicant.
- The proposal is complete and includes all the supporting documents.

2.2 ELIGIBILITY CRITERIA

The following will be verified:

- The applicant and in case of consortium also its partner/s are on the list of competent organisations designated by the Member States in accordance with Art 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004. This list is regularly updated by EFSA Management Board. Applicants or partners not currently on the list may apply to be included but they must be formally accepted and included on the Art 36 list by the EFSA Management Board before the deadline for proposals for this call.
- Applicant and, in case of consortium, also partner/s are involved in the execution of the project.
- The applicant/partner is to be involved with its own staff in the execution of the tasks, with no subcontracting foreseen.

Documents to be provided:

- **LEGAL ENTITY FORM (Annex 3)** (download template here) to be completed and signed by the applicant and in case of consortium also by its partner/s. For a public body this legal entity form should be provided together with a copy of the resolution or decision establishing the public body, or other official document establishing that public body. For a private body an extract from the official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical only one of these documents is required).
- **FINANCIAL IDENTIFICATION FORM (Annex 4)** (download template here) to be completed only by the applicant and in case of consortium only by the coordinator.

Please note that there is no need to submit these forms if they have already been submitted under another EFSA procurement or grant procedure and provided that these forms are still

valid. In this case simply indicate in the application form the reference of the call under which the form/s were submitted to EFSA.

The following is applicable only if the applicant is a consortium:

- **PARTNERSHIP STATEMENT**: it is required that the applicant and partner/s provide EFSA with this statement in which they indicate their technical and financial involvement. The applicant and partner/s must sign this partnership statement. No template is provided by EFSA.

2.3 EXCLUSION CRITERIA

The applicant and partner/s must sign a declaration on their honour certifying that they are not in one of the exclusion situations referred to in the Articles 136-140 of EU Financial Regulation as listed therein.

Documents to be provided:

- **THE DECLARATION ON HONOUR FOR EXCLUSION CRITERIA (Annex 5)**: template is published together with this Call; to be completed/signed individually by the applicant and by each of the partners.

2.4 SELECTION CRITERIA

The purpose of the selection criteria is to verify the financial and operational capacity of the applicant and in case of a consortium also of its partner/s.

Financial capacity:
The applicant and in case of consortium also its partner/s must have stable and sufficient financial resources to:

- maintain their activity throughout the period during which the project is being carried out, and
- participate in its funding.

Operational capacity:

The applicant or in case of a consortium, the consortium as a whole, must have the technical and professional capacity necessary to complete the proposed project:

Professional and technical requirements:

The organization/s:

1) The applicant or in case of a consortium, the consortium as a whole, needs to have relevant expertise in good laboratory practise fields including, quality assurance, study monitoring activities.

The team should be composed by at least 3 experts covering the following requirements:

2) The team of experts involved in the project must have educational background/university degree in life sciences, biology, toxicology, chemistry or any other related science;

3) The team of experts involved in the project must have the following technical competencies:
   a) methods and best practices related to GLP, quality assurance, study monitoring applied to non-clinical safety testing of regulated products.
   b) methods and best practices related to analytical and physical-chemical testing, molecular characterisation, animal nutrition, toxicological studies (including genotoxicity, mammalian toxicology, ecotoxicology), environmental fate studies, residue studies, field studies.
   c) Knowledge in relevant OECD test guidelines and other guidelines, ISO standards is requested.

4) The team of experts involved in the project must have overall a very good level of spoken and written English (level B2 and above). For non-native speakers, this should be demonstrated by an Official certificate of English proving a B2 level or at least 3 years of work/study in an English-speaking environment or at least 3 years of experience working in projects where English is the working language.

Documents to be provided by the applicant:

- **Generic evidence: THE DECLARATION ON HONOUR ON SELECTION CRITERIA (Annex 6).**
- **Generic evidence (if applicable):** Additional document for private bodies only: to be submitted only if the grant requested from EFSA is > 60.000 €: **SIMPLIFIED FINANCIAL STATEMENT** (**Annex 7**) (template available at EFSA's website, published together with this Call) completed for at least last 2 closed financial years.
- **Evidence requested for professional and technical requirements**:
  - ✓ For requirement 1: **THE INSTITUTION PROFILE** for all the organisations involved in the project. The institution profile must contain the list of **at least 3 relevant projects and/or publications** related to objectives of this call carried out and/or published in the course of the past 10 years.
  - ✓ For requirements 2, 3 and 4: **A summary table** and **THE CURRICULUM VITAE** - preferably in Europass format - of the experts and other staff intended to be involved in the project, including for each member a brief summary of the relevant expertise, for requirements 2, 3 and 4. In addition, a **list of publications** relevant to the project needs to be submitted.
- **Generic evidence (if applicable): LETTER OF COMMITMENT:** applicable only in the case when other public body financially contributes to the project (body other than EFSA, applicant or in case of consortium, its partners); to be signed by the contributing public body; it serves to confirm its commitment to financially contribute to the project; no template is provided by EFSA.
- **Institutional and Individuals declaration of interests** available here
  EFSA will request Institutional and Individuals DoIs only from the awarded beneficiary, prior to the signature of the grant agreement. The requirement to submit Institutional and Individual DoIs will be specified in the award letter and will have to be provided and assessed by the EFSA Authorising Officer before and as a condition of grant agreement signature. **Institutional and Individual DoIs do not need to be provided with your proposal at this stage.**
  In case of a consortium, such declarations will need to be completed separately and submitted for each partner and for each individual member of the project team coming from consortium partners.
  Please refer to EFSA's policy on independence and the Decision of the Executive Director on Competing Interest Management for more detailed information.

2.5 AWARD CRITERIA

The award criteria serve to assess the quality of the proposals submitted in the light of the objectives and priorities set and of the expected results and make it possible to award the grant to the action which, in accordance with Article 199 of the Financial Regulation, maximises the overall effectiveness of the Union funding.

A) QUALITY AWARD CRITERIA

1. The extent to which **the project is described in detail and is of high quality** in relation to the proposal for development of the fit for purpose GLP verification methodology and tools, to the performance of GLP testing pilot study (**MAX 25 POINTS).**
2. The extent to which **the project is described in detail and is of high quality** in relation to the proposal for development of GLP training program for EFSA staff/experts/contractors and Member States. (**MAX 25 POINTS).**
3. The extent to which the proposal **achieves the specific objectives of this call** and is likely to deliver reliable results of development, testing and refinement of the GLP verification methodology and tools for the targeted number of studies assigned by EFSA (**MAX 25 POINTS)**.
4. **Project programme description clarity**, including phases, detailed description of all activities, tasks/subtasks, clear timelines for the project tasks completion, detailed milestones per task (e.g. via a project Gantt chart), description of identified risks and proposed mitigating actions; proposed contingency plan in case of deviations from the project programme; task distribution among consortium partners (if applicable) and individual team members (**MAX 25 POINTS)**.

The sum of all quality award criteria gives a maximum possible total of **100 points**.

Proposals must score a **minimum of 70 points overall** out of the maximum possible 100 points to pass the quality threshold.

Applicants must provide a detailed technical proposal addressing all points in this call for proposals and each of the quality award criteria. Repetition of mandatory requirements in the call for proposals without providing further detail will only result in a very low score.

2.6 PROCESS FOLLOWING THE ASSESSMENT AGAINST AWARD CRITERIA

The applicant(s) will be notified, once the evaluation has been finalized, whether they are placed or not on the reserve list.

EFSA reserves the right to invite the 1st ranked applicant on the reserve list, to adapt its proposal based on the evaluators' comments.

Following the successful conclusion of the adaptation phase, the award decision will be taken by EFSA. Subsequently, the grant agreement will be prepared.

If the 1st ranked applicant fails to adapt its proposal, EFSA reserves the right to reject the funding. The budget made available in this way may be used for a project of the next ranked applicant on the reserve list.

3. SUBMITTING PROPOSALS

3.1 APPLICATION FORM

The proposal must be submitted using the **EFSA APPLICATION FORM (Annex 2).** The application form is published together with this call and must be:

- duly completed in all its parts;
- supported with all the requested annexes;
- signed by a duly authorised legal representative of the applicant.

Please note that, by submitting the proposal, the applicant and in case of consortium also its partner/s accept/s the procedures and conditions as described in this Call and in the documents referred to in it.

In addition to a full paper version of the application the applicant shall submit the application also on a CD/USB data storage format. The electronic version must be identical to the paper version. In case of any discrepancies between the electronic and paper version, the latter will prevail. All documents presented by the applicant become the property of EFSA and are deemed confidential.

3.2 LANGUAGE OF THE PROPOSAL AND THE SUPPORTING DOCUMENTS

Proposals may be submitted in any official language of the European Union. However, as EFSA`s working language is English, the submission of proposals in English would speed up the evaluation process.

Please note that some supporting documents are required in support of the proposal. These supporting documents are an integral part of the proposal. For more information on the relevant supporting documents to be submitted with the proposal, please refer to part 2 of this Call. If these supporting documents are in a language other than English, in order to facilitate and speed up the evaluation, it would be appreciated if a reliable translation of the relevant parts of the documents into English is provided with the proposal.

3.3 SUBMISSION MODALITIES

Proposals can be submitted as indicated in the second page of this document in the Indicative procedure timetable (Call for Proposals and guide for Applicants).

3.5 EXPECTED DURATION OF PROCEDURE

Information on expected duration of procedure – time to grant:

- Applicants will be informed on the decision regarding their application at the latest by 6 months since the deadline for submission of proposals.
- Signature of the grant agreement will take place at the latest by 3 months since the successful applicant/s has/have been informed on the decision on their application.

Annex 8

DECLARATION CONCERNING CONFIDENTIALITY AND PERSONAL DATA PROTECTION

I, the undersigned [*insert name/surname*], in my quality as employee of [*insert name of Grant Agreement beneficiary organisation*] and performing tasks for EFSA, in the context of Grant Agreement GP/EFSA/FDP/2022/02, **hereby declare** to be aware that under Article II.6 of the Grant Agreement signed between EFSA and my employer, there is an obligation to comply with strict confidentiality requirements, and **I hereby commit**:

1. To respect confidentiality of any information or document acquired in the context of my work at EFSA. The obligation to respect confidentiality in particular pertains to [*as needed, please insert a reference to sensitive activity(ies), appropriate to be specifically mentioned in this declaration*];
2. Not to divulge, publish or otherwise make available to any third party outside EFSA any information received from EFSA or acquired as a result of my work at EFSA, either during or after the completion of my assignment at EFSA, without the written prior consent of EFSA;
3. To process the information and documents received in a secure digital environment, in particular in accordance with the standards, rules and procedures in place at EFSA and shared in the frame of the execution of the grant agreement.
4. To respect the confidential nature of any opinions expressed by any person in the context of my work at EFSA, orally or in written form, including opinions of external experts, other grant beneficiaries and contractors;
5. Not to use or misuse any information acquired in the context of my work at EFSA for any other use than the one subject to this grant agreement and in particular for any personal benefit or that of any third party;
6. To be aware that there are legal consequences in case of violation of the confidentiality provisions hereby set out;
7. To carry out the duties and conduct myself with the interests of EFSA in mind. I shall execute the tasks entrusted, in accordance with EFSA procedures, regulations and standards shared with me in the performance of these tasks and shall comply with them objectively and impartially and independently.
8. That on completion of my work at EFSA all paperwork and other materials acquired in the context of my work at EFSA as well as copies of such are returned to EFSA;
9. That on completion of my work at EFSA I will delete all information from any computers, electronic media or similar devices on which I archived or programmed that information or data, in so far as deleting this data does not conflict with any legal requirements which my employer must observe.

As set out in article II.7 of the Grant Agreement signed between EFSA and my employer, EFSA adheres to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC.

I hereby commit:

10. That if I receive personal data in the context of my assignment at EFSA, I shall process these solely for the purpose for which these were transmitted to me;
11. That I shall act only on instruction of EFSA, in its capacity of controller with regard to any personal data processing in the context of my assignment with EFSA;
12. That I shall follow the specific instructions of EFSA in the case of transfer of personal data to any third party, therefore observing appropriate security safeguards to avoid unauthorised processing and disclosure.

I am aware **this undertaking is not limited in time** and I hereby certify that I have read all of the above clauses and that I am aware to be accountable for correct and responsible use of the data and data access systems.

NAME: _____

SIGNATURE: _____

DATE: _____

This signed declaration must be provided to EFSA for further processing, prior to the performance of tasks under the grant agreement.

EFSA reserves the right to update this declaration at any time during the implementation of the grant agreement and to request an updated signature from signatory.